



January 13, 2005

United States
Department of
Agriculture

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 05-01

Animal and Plant
Health Inspection
Service

Subject: Mouse Safety Testing

Veterinary Services

To: Biologics Licensees, Permittees, and Applicants
Veterinary Services Management Team
Directors, Center for Veterinary Biologics

Center for Veterinary
Biologics

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The purpose of this notice is to inform interested parties that the Center for Veterinary Biologics (CVB) is in the process of reviewing regulations requiring the intracerebral inoculation of mice in the mouse safety test outlined in 9 CFR 113.33.

Currently, the mouse safety test described in 9 CFR 113.33(a)(1) for live virus vaccines requires that two groups of mice be inoculated with vaccine, one group intracerebrally and one group intraperitoneally. Current standards for extraneous agent testing of Master Seed viruses, in addition to animal welfare concerns, have prompted review of this regulation. We are currently considering revision of the regulation to require only the intraperitoneal or subcutaneous inoculation of mice, with satisfactory test criteria being that none of these inoculated mice demonstrate unfavorable reactions. This proposed revision would be consistent with the requirements for liquid products, including antisera and bacterins, outlined in 113.33(b).

CVB will allow exemptions to the 9 CFR 113.33(a) testing requirements until the regulations are revised. Requests for exemptions to these regulations should be addressed to the reviewer assigned to the establishment.

/s/ Richard E. Hill, Jr.

Richard E. Hill, Jr.
Director
Center for Veterinary Biologics